

PATENT ATTORNEY DOCKET NO. 061266-5008-02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re.	Application of:)
U.S. Patent No. 5,290,551)
	Issue Date: March 1, 1994)
	Filing Date: December 4, 1992)
Reissue Application No.: 09/036,645)
10100)
For:	Treatment of Melanoma with a Vaccine)
	Comprising Irradiated Autologous Melanoma)
	Tumor Cells Conjugated to a Hapten	

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

REISSUE DECLARATION BY THE INVENTOR

I hereby declare that:

- 1. My residence, mailing address and citizenship are stated below next to my name.
- 2. I believe that the inventor named below is the original and first inventor of the subject matter which is described and claimed in United States Patent No. 5,290,551 (the "'551 patent"), issued on March 1, 1994 and for which a reissue patent is sought on the invention entitled: Treatment of Melanoma with a Vaccine Comprising Irradiated Autologous Melanoma Tumor Cells Conjugated to a Hapten, the specification of which was attached to the original Declaration filed on March 6, 1998.
- 3. I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment made during the prosecution of the application and any amendment submitted concurrently herewith.
- 4. I assigned the entire title to the '551 patent, granted to me on March, 1994, for Treatment of Melanoma with a Vaccine Comprising Irradiated Autologous Melanoma Tumor Cells Conjugated to a Hapten to Thomas Jefferson University, by an assignment recorded in the United States Patent and Trademark Office on July 6, 1990, at Reel 5336, Frame 880.

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- 5. I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. §1.56.
- 6. I verily believe the original patent to be wholly or partly inoperative or invalid by reason of the patentee claiming more or less than the patentee had the right to claim in the patent.
- 7. At least one error upon which this reissue application is based is described as follows:
 - (a) As issued, claim 1 of the '551 patent is directed to vaccine for treatment of melanoma that includes "irradiated autologous melanoma cells conjugated to a hapten, said hapten selected from the group consisting of dinitrophenyl, trinitrophenyl, and N-iodoacetyl-N'-5 sulfonic 1-naphtyl ethylene diamine, and mixed with an immunological adjuvant, wherein said immunological adjuvant is Bacille Calmette-Guerin." Claim 2 depends from claim 1.
 - (b) An abstract entitled "Tumor Inflammatory Response Induced by Immunization with Autologous Melanoma Cell Conjugated to Dinitrophenol (DNP)" published in Proc. Am. Assoc. Cancer Res., v. 30, March 1989 (the "Abstract"), was not cited to the United States Patent and Trademark Office during prosecution of the '551 patent, even though it was published more than one year prior to the patent's priority date of May 8, 1990. This oversight was not a result of any deceptive intent on the part of the applicant.
 - At the time that the '551 patent was being prepared for filing, I believed that the Abstract was first made public at the 80th Annual Meeting of the American Association for Cancer Research (the "AACR Meeting"), held in San Francisco on May 24-27, 1989, which was less than one year before the priority date of the '551 patent. I did not appreciate that the Abstract was published by the AACR Meeting before the meeting date, nor that the actual publication of the Abstract was prior to May 8, 1989. Thus, I did not advise the Patent Office, my attorneys, or anyone else that the publication date for the Abstract was earlier than the AACR Meeting. I now realize that it was an error to overlook the Abstract publication date, and it was an error not to inform the Patent Office of the Abstract. This error was made without deceptive intent on the part of the applicant.
 - (d) Claim 1 of the present reissue application has been amended such that it claims subject matter that does not read on the Abstract, as follows:
 - (1) The Markush group of haptens includes dinitrophenyl (DNP). Claim 1 has been amended to delete this term.

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- Accordingly, reissue claim 1 seeks to amend claim 1 as follows: (e)
 - 1. (Amended) A vaccine useful for the treatment of melanoma comprising irradiated autologous melanoma cells conjugated to a hapten, said hapten selected from the group consisting of dinitrophenyl, trinytrophenyl [,] and N-iodoacetyl-N'-5 sulfonic 1-naphtyl ethylene diamine; and mixed with an immunological adjuvant, wherein said immunological adjuvant is Bacille Calmette-Guerin.
- All errors corrected in this reissue application, up to the time of the filing of this reissue 7. declaration, arose without any deceptive intention on the part of the applicant.
- I hereby declare that all statements made herein of my own knowledge are true and that 8. all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this declaration is directed.

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